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The authority of next-of-kin in explicit and presumed consent systems for deceased organ donation: an analysis of 54 nations

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Abstract

Background. The degree of involvement by the next-of-kin in deceased organ procurement worldwide is unclear. We investigated the next-of-kin's authority in the procurement process in nations with either explicit or presumed consent.

Methods. We collected data from 54 nations, 25 with presumed consent and 29 with explicit consent. We characterized the authority of the next-of-kin in the decision to donate deceased organs. Specifically, we examined whether the next-of-kin's consent to procure organs was always required and whether the next-of-kin were able to veto procurement when the deceased had expressed a wish to donate.

Results. The next-of-kin are involved in the organ procurement process in most nations regardless of the consent principle and whether the wishes of the deceased to be a donor were expressed or unknown. Nineteen of the 25 nations with presumed consent provide a method for individuals to express a wish to be a donor. However, health professionals in only four of these nations responded that they do not override a deceased's expressed wish because of a family's objection. Similarly, health professionals in only four of the 29 nations with explicit consent proceed with a deceased's pre-existing wish to be a donor and do not require next-of-kin's consent, but caveats still remain for when this is done.

Conclusions. The next-of-kin have a considerable influence on the organ procurement process in both presumed and explicit consent nations.

Keywords: consent; deceased donor; health policy; law; next-of-kin

Introduction

There is a global organ shortage while the number of individuals on waiting lists continues to grow [1–4]. In 2010, 4529 Canadians were on the waiting list and 247 died waiting [5]. Similarly, there are currently 7686 individuals in the UK on the waiting list and 111 105 such individuals in the USA [6, 7]. To address this organ shortage, policy makers in various nations have debated the merits of legislative changes to consent policies for organ donation after death [8-10]. One strategy that has been vigorously debated in several nations is the implementation of 'presumed consent' for deceased organ donation. Presumed consent, sometimes referred to as the 'opt-out' approach, is a legislative organ donation policy that assumes an individual has a desire to donate unless he or she makes a statement of objection to donation. In contrast, explicit consent policies such as 'first person consent' require an individual to 'opt-in' by proactively affirming a desire to be a donor such as signing a donor card or indicating donor status on a driver's license.

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Otherwise the next-of-kin is consulted to determine the deceased's preferences with respect to deceased organ donation.

Nations with presumed consent have higher rates of deceased organ donation when contrasted to nations with explicit consent [11–13]. However, some authors remain unconvinced that presumed consent legislation alone explains this variation [14, 15]. There has also been resistance by the North American public to the idea of switching to an opt-out system [16, 17]. Interestingly, there is considerable range in the proportion of family members who refuse donation in both explicit and presumed consent nations, and both consent systems have an average family refusal rate of 34-38% [18]. However, data on family refusals are very limited, and values are not available for all nations. Due to the nature of deceased donation, the next-of-kin are often relied on by transplant officials in the organ procurement process. We set out to determine whether there are similarities across the two consent systems in how the nextof-kin are involved in the decision to donate after death. Specifically, we examined whether in practice nations always require the next-of-kin's consent to procure organs, and whether the next-of-kin were able to veto procurement when the deceased had expressed a wish to donate. We collected data from 54 nations to compare and contrast the authority of next-of-kin in explicit and presumed consent systems for deceased organ donation.

Materials and methods

Definitions of presumed and explicit consent

We used World Health Organization definitions of presumed and explicit consent [19]. Explicit consent is defined as a system in which 'cells, tissues or organs may be removed from a deceased person if the person had expressly consented to such removal during his or her lifetime'. Presumed consent is defined as a system that 'permits material to be removed from the body of a deceased person for transplantation and, in some countries, for anatomical study or research, unless the person had expressed his or her opposition before death by filing an objection with an identified office or an informed party reports that the deceased definitely voiced an objection to donation'. Some nations have also proposed a 'soft' presumed consent law, where the next-of-kin is still involved in the donation decision [20].

Eligible nations

Our data of interest, next-of-kin involvement in deceased organ donation in nations with presumed and explicit consent, are presented in Figure 1.

We first considered all nations where deceased organ donation is practiced as identified by the World Health Organization. We collected relevant transplant legislation and/or guidelines from each nation and categorized each nation as either presumed or explicit consent [19]. Foreign language legislation was translated into English. An example of a deceased donation clause that was interpreted as presumed consent was 'if a deceased person did not express objection, when alive, it is allowed to recover cells, tissues or organs from such person human cadaver for transplantation purposes [21]'. An example of an explicit consent clause was 'any person who has attained the age of 16 years may consent, (i) in writing signed by the person at any time or (ii) orally in the presence of a least two witnesses during the person's last illness that the person's body or the part or parts thereof specified in the consent be used after the person's death for therapeutic purposes, medical education or scientific research [22]'. For nations with state level legislation, attempts were made to obtain each state's legislation to determine if there was a difference in consent policies between states.

Data collection

Data collection occurred from May 2009 to August 2010. Data were independently abstracted by a single author (A.M.R.) from government websites, legal databases and kidney, nephrology and transplantation foundations' websites. Data were then independently reviewed by a second author (L.D.H.) for accuracy. Our categorization of each nation as presumed or explicit consent was verified with a second source, such as a published scientific article (Supplementary Appendix 1). In most cases, we also collected information directly from health professionals via electronic mail to ensure proper classification of the nation's consent principle, confirm the appropriate legislation was collected and gain insight into the daily practices of deceased organ procurement (Supplementary Appendix 2). We gathered information to characterize the authority of the next-of-kin in the donation decision, specifically whether nations always required the next-of-kin's consent and whether a validly recorded wish to be a donor was fulfilled. Electronic mail was utilized because of its ability to provide a clear paper trail and help reduce language misinterpretations. Telephone calls were utilized when requested, after which a follow-up email summarizing the call was sent back to the health professional for member checking. Health professionals included members of national kidney, nephrology and transplant foundations, ministry of health personnel and transplant staff. We sent all findings back to health professionals via electronic mail for review to ensure data quality and accuracy.

Results

We obtained data from 49 (75%) of the 65 nations reported to have active deceased organ donation programs by the World Health Organization (Supplementary Appendix 3) [M. Carmona (personal communication)]. An additional five nations (Armenia, Belarus, Costa Rica, Ecuador and Malta) were found through contact with nation

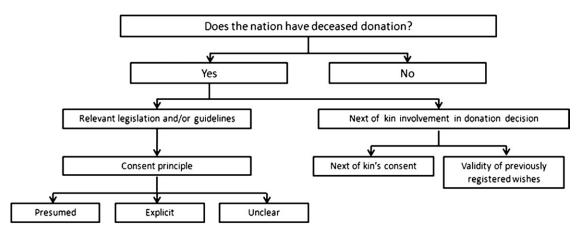


Fig. 1. Flow diagram of data collected for each eligible nation.

Table 1. Legislation by nation^a

Nation	Province/Territory/ State/Region	Name of legislation	Consent Source	Source type
Armenia		Law on Organ and Tissue Transplantation, 2002	of Armenia [23] (Hovhannisyan,	Website and personal communication
Australia	Australian Capital Territory New South Wales Northern Territory Queensland South Australia Tasmania Victoria Western Australia	Transplantation and Anatomy Act 1978 Human Tissue Act 1983 Human Tissue Transplant Act 1979 Transplantation and Anatomy Act 1979 Transplantation and Anatomy Act 1983 Human Tissue Act 1985 Human Tissue Act 1982 Human Tissue and Transplantation Act 1982	Register [24] New South Wales Government [25] Northern Territory Government— Department of the Chief Minister [26] Queensland Government—Office of the Queensland Parliamentary Counsel [27] Government of South Australia—Attorney-General's Department [28] Tasmania's Consolidated Legislation Online [29] Victoria Government Health Information [30]	Website Website Website Website Website Website Website Website
Austria		Hospitals Law of 18 December 1956, Paragraph 62a-e, 1982	Presumed Gesundheit Österreich GmbH [32]	Website
Belarus		Law of the Republic of Belarus 'On Transplantation of Human Organs and Tissues'		Personal communication
Belgium		Law of 13 June 1986	, , , , , , , , , , , , , , , , , , ,	Website
Brazil		Law No. 9.434 of 4 February 1997 Law No. 10.211 of 23 March 2001 Decree No. 2.268 of 30 June 1997	Explicit Ministério da Saúde [34–36]	Website

Continued

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Table 1. Continued

Nation	Province/Territory/ State/Region	Name of legislation	Consent	Source	Source type
Canada	Alberta British Columbia Manitoba New Brunswick Newfoundland	Human Tissue and Organ Donation Act, 2006 Human Tissue Gift Act 1996 Human Tissue Gift Act, 1987 Human Tissue Gift Act, 2004 Human Tissue Act, 1990	Explicit	CanLII Database [22, 37–48]	Website
	Nova Scotia Nunavut Ontario	Human Tissue Act, 1988 Human Tissue Gift Act, 1989 Human Tissue Act, 1988 Trillium Gift of Life Network Act, 1990 Human Tissue Donation Act, 1988 Civil Code of Quebec Human Tissue Gift Act, 1978 Human Tissue Gift Act, 2002			
Chile		Law No. 20.413 of January 6, 2010	Presumed	d ^d Biblioteca del Congreso Nacional de Chile [49]	Website
Colombia		Law No. 9, 1979 Law No. 73, 1988 Law No. 919, 2004 Decree 2493, 2004 Resolution 2640, 2005	Presumed	d Punta Cana Group [50]	Website
Costa Rica		Law No. 7409 of 27 October 1994	Presumed	d Punta Cana Group [50]	Website
Croatia		Law RH 50/88 Law RH 177/2004 Rule No. 152/2005	Presumed	d Donor Network of Croatia [51]	Website
Cuba		Law No. 41 of 13 July 1983 on public health	Explicit	Legislative Responses to Organ Transplantation [52]	Book
		Decree No. 139 of 4 February 1988		Trasplante [53]	Website
Czech Republic		Act 285/2002 Coll. Of 30 May 2002 on donation, removal, and transplantation of organs and tissues	Presumed	d Transplants Coordinating Center (KST) (Fryda, P. Prague. March 2010)	Personal communication
Denmark		Sundhedsloven – LBK No. 95 of 7 February 2008	Explicit	Retsinformation [54]	Website

Table 1. Continued

Nation	Province/Territory/ State/Region	Name of legislation	Consent	Source	Source type
Ecuador		Law No. 58 of 27 July 1994	Presumed	Instituto Ecuatoriano de Dialisis y Trasplantes (Ortiz-Herbener, F. Guayaquil. July 2009)	Personal communication
Estonia		Rakkude, Kudede Ja Elundite Käitlemise Ja Siirdamise Seadus	Explicit	Electronic Riigi Teataja (ERT) [55]	Website
Finland		No. 101/2001 Act on the medical use of human organs and tissues Law No. 547 of 11 May 2007 amending Law No. 101	Presumed	1 Finlex [56, 57]	Website
France		Public Health Code	Presumed	1 Legifrance [58]	Website
Germany		The Transplantation Act, 5 November 1997	Explicit	Deutsche Stiftung Organ transplantation (Norba, D. June 2009. Frankfurt) Bundesgesetzblatt online [59]	Personal communication
		Amendments to the Transplantation Act, 2007			Website
Iceland		Act No. 16 of 6 March 1991	Explicit	Althingi [60]	Website
India		Act No. 42 of 1994, Transplantation of Human Organs Act	Explicit	CommonLII [61] MOHAN Foundation [62]	Website
		Transplantation of Human Organs (Amendment) Rules 2008		MOTAN Foundation [62]	Website
Ireland		n/a	Explicit	n/a	n/a
Israel		Organ Transplant Act, 2008	Explicit	Israel Ministry of Health (Ashkenazi, T. Tel Aviv. May 2010)	Personal communication
Italy		Law No. 91 of 1 April, 1999 Ministerial Decree of 8 April 2000	Presumed	l Portale Della Normativa Sanitaria [63, 64]	Website
Japan		Law No. 104 of 16 July 1997 ^e	Explicit	WHO International Digest of Health Legislation [65]	Website

Table 1. Continued

Nation	Province/Territory/ State/Region	Name of legislation	Consent	Source	Source type
Kuwait		Decree-Law No. 55 of 20 December 1987	Explicit	Legislative Responses to Organ Transplantation [52]	Book
Lithuania		Law on Donation and Transplantation of Human Tissues, Cells and Organs	Explicit	Lithuanian National Transplantation Bureau (NTB) [66]	Website
Luxembour	9	Law of 25 November 1982	Presumed	Luxembourg-Transplant [67]	Website
Malaysia		Human Tissues Act 1974	Explicit	The Attorney General of Malaysia [68]	Website
Malta		n/a	Explicit	Transplant Support Group (Debattista, A. Hamrun. June 2010)	Personal communication
Mexico		Ley General de Salud Reglamento de la Ley General de Salud Lineamientos para la asignación y distribución de órganos y tejidos	Explicit	Centro Nacional de Trasplantes [69]	Website
Netherlands		The Organ Donation Act, 1996	Explicit	Overheid [70]	Website
New Zealan	d	Human Tissue Act 2008	Explicit	The Parliamentary Counsel Office (PCO) [71]	Website
Norway		Law No. 6 of 9 February 1973	Presumed	Lovdata [72]	Website
Paraguay		Law No. 1246/98	Presumed	Punta Cana Group [50]	Website
Philippines		Republic Act No. 7170	Explicit	Chan Robles Virtual Law Library [73]	Website
Poland		The Cell, Tissue and Organ Recovery, Storage and Transplantation Act, 2005	Presumed	Poltransplant [21]	Website
Romania		Law No. 95/2006	Explicit	Agenţtia Natională de Transplant [74]	Website

Table 1. Continued

	Province/Territory/				
Nation	State/Region	Name of legislation	Consent	Source	Source type
Russia		Law of 22 December 1992	Presumed	Central Clinical Hospital of Russian Academy of Sciences (Pishchita, A. Moscow. June 2010)	Personal communication
Saudi Arab	ia	Procedure of Deceased Organ Donation	Explicit	Saudi Center for Organ Transplantation [75]	Website
Singapore		Human Organ Transplant Act	Presumed	Singapore Statutes Online [76, 77]	Website
		The Medical (Therapy, Education and Research) Act			
Slovak Republic		Law 576/2004, of 21 October 2004	Presumed	Slovenské Centrum Orgánových Transplantácií [78]	Website
Slovenia		The Removal and Transplantation of Human Body Parts for the Purposes of Medical Treatment Act	Presumed	Uradni list RS [79]	Website
South Afric	ca	National Health Act, 2003	Explicit	Department of Health [80]	Website
South Kore	ea	Law 8852	Explicit	Ulsan University Medical College (Kim, J. H. Seoul, June 2010)	Personal communication
Spain		Law No. 30 of 27 October 1979 RD 2070/1999 on the removal and transplantation of organs	Presumed	Global Observatory on Donation and Transplantation [81]	Website
Sweden		Law No. 831 of 1 June 1995	Presumed	Riksdag [82]	Website
Switzerland	i	Federal Act of 8 October 2004 on the Transplantation of Organs, Tissues and Cells (Transplantation $Act)^f$	Explicit	The Federal Authorities of the Swiss Confederation [83]	Website
Thailand		Rules of the Medical Council on the Observance on Medical Ethics	Explicit	Chulalongkorn University (Nivatvongs, S. Bangkok. June 2010)	Personal communication
		Medical Council's Announcement on Criteria for Brain Death Diagnosis			
Tunisia		Law No. 91-22 of 25 March 1991 Law No. 49 of 12 June 1995 Law No. 18 of 1 March 1999 Decree No. 97 of 13 June 1997 Ordinance of 28 July 2004	Presumed	CHU la Rabta (Hamouda, C. Tunis. June 2010)	Personal communication

Table 1. Continued

Nation	Province/Territory/ State/Region	Name of legislation	Consent	Source	Source type
Turkey		Law #2238 of 29 May 1979 Law #2594 of 21 January 1982	Presume	d Turkish Transplantation Society [84]	Website
UK		Human Tissue Act 2004 ^g Human Tissue (Scotland) Act 2006	Explicit	Office of Public Sector Information [85, 86]	Website
USA		Uniform Anatomical Gift Act ^h	Explicit	National Conference of Commissioners on Uniform State Laws [87]	Website
Venezuela	ı	Law of 3 December 1992	Explicit	Punta Cana Group [50]	Website

an/a = not applicable.

^bSwitched to 'soft' presumed consent March 2009.

cRemoved a clause that allowed next-of-kin to object to donation in the absence of a registered wish to donate February 2007. In practice next-of-kin's objection still respected in absence of a registered decision.

^dChanged from explicit consent to presumed consent January 2010.

^eIn July 2009 revisions were adopted that will be in effect in 1 year [R. Ida (personal communication)].

A federal law was in enacted July 2007 abolishing the previous mixture of presumed and explicit consent canons (states).

^gApplies to England, Wales and Northern Ireland.

^hThe most recent version of the UAGA has been implemented in the various states. A list can be found at http://www.anatomicalgiftact.org.

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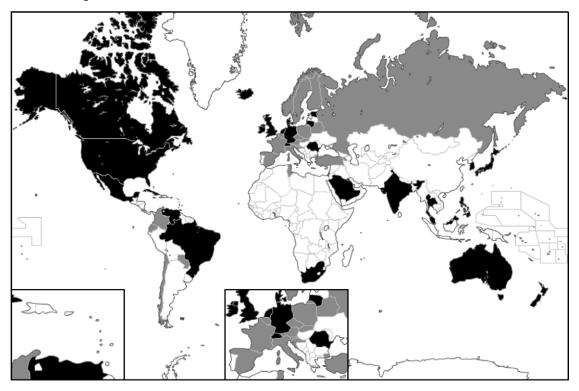


Fig. 2. 54 nations studied. Explicit consent nations in black, presumed consent countries in gray.

representatives to also have deceased organ donation, so the total number of countries included in this review was 54 (Table 1, Figure 2). For the 16 missing nations, data collection was incomplete either because the required information was not available and/or because the health professional was non-responsive.

Legislation

Of the 54 nations, 25 have presumed consent and 29 have explicit consent. As detailed in Table 1 the consent principle has been changed or modified in five nations in recent years (Armenia, Belgium, Chile, Japan and Switzerland). We focused on their most current practice for this report. Two countries (Ireland and Malta) do not have official legislation regarding deceased organ donation, but both were operating under explicit consent when the study was conducted.

Role of next-of-kin in decision making

Nations with presumed consent. In all 25 nations with presumed consent, next-of-kin are informed of the intention to recover organs (Table 2). Variations exist in Austria and Russia, where it is necessary for the next-of-kin to be physically present in the hospital at the time of procurement to object to donation. All presumed consent nations provide a method for individuals to opt-out of donation. In addition, 19 of the 25 nations with presumed consent also provide a mechanism for individuals to register their wishes to be a donor, such as affirmative registration in an electronic registry. We found that 21 of the 25 presumed consent

nations allow the next-of-kin to object and prevent a potential donation. In the other four nations (Belgium, France, Poland and Sweden) health professionals do not override the deceased's registered wish to be a donor in the case of an objection from next-of-kin but will respect an objection if there is no such record. Exceptions and caveats to these practices are presented in Table 2.

Nations with explicit consent. In all 29 nations with explicit consent, the next-of-kin are approached regardless of whether the wishes of the deceased are known or not. In all 29 nations, authorization from the next-of-kin is required for organ procurement if the deceased's wishes are unknown (Table 3). In cases where the deceased validly registered their wish to become a donor, procurement will occur in four nations without requiring next-of-kin's authorization (the Netherlands, Romania, UK and most of the USA). However, there are exceptions and changes occurring in all four nations, presented in Table 3.

Discussion

Several nations have debated the merits of changing the consent principle of deceased donation legislation from explicit to presumed consent [88–91]. Presumed consent nations have been shown to have statistically higher rates of deceased donation than explicit consent nations [11–13]. However, even supporters of presumed consent legislation concede that it is one of the more controversial strategies to improving donation rates in explicit consent nations, and it could divert attention and efforts from other proven

Table 2. Role of next-of-kin in presumed consent nations

Nation	Next-of-kin informed	Next-of-kin's authorization required if wishes are unknown ^a	Next-of-kin can veto donation
Armenia	Yes	n/a	Yes
Austria	Yes ^b	n/a	Yes ^b
Belarus	Yes	n/a	Yes ^c
Belgium	Yes	No^d	No ^e
Chile	Yes	n/a	Yes ^f
Colombia	Yes	Yes ^g	Yes
Costa Rica	Yes	Yes ^g	Yes
Croatia	Yes	Yes	Yes
Czech Republic	Yes	n/a	Yes
Ecuador	Yes	Yes	Yes
Finland	Yes	Yes	No ^e
France	Yes	No^h	Yes
Italy	Yes	Yes	Yes
Luxembourg	Yes	Yes	Yes
Norway	Yes	Yes	Yes
Paraguay	Yes	Yes	Yes
Poland	Yes	No ^h	Yes
Russia	Yes ^b	Yes ^b	Yes ^b
Singapore	Yes	Yes	No ^e
Slovak Republic	Yes	n/a	Yes
Slovenia	Yes	Yes	Yes ⁱ
Spain	Yes	Yes	Yes
Sweden	Yes	No ^j	No ^e
Tunisia	Yes	Yes	Yes
Turkey	Yes	Yes	Yes

^a'Wishes Unknown' refers to nations that provide a method for individuals to express a desire to be a donor in addition to a method to objecting to deceased donation. Nations that do not provide such a means are marked not applicable (n/a).

strategies [92]. Indeed, studies conducted on both the Canadian and American public demonstrate a resistance to switching to this type of consent system [16, 17]. The importance of public support for such a legislative change was exemplified by Brazil's unsuccessful implementation of presumed consent, which resulted in the policy being reverted back to explicit consent [93]. There has also been a recent call for research on personal-level factors that may affect deceased donation rates, particularly the role of next-of-kin [94].

To address this need, we conducted a global review to better understand the authority next-of-kin have in the decision to pursue deceased organ donation in nations with presumed and explicit consent. The results of this study help inform the current debate as to whether nations with explicit consent should consider a switch to presumed consent legislation to improve their deceased organ donation programs. Organ procurement systems are complex with key differences between what is legislated and what is done in practice. We found that many nations with presumed

consent legislation follow a much softer system of consent in reality, which almost always includes next-of-kin in the decision making. The next-of-kin have a considerable influence over the decision to procure organs in both presumed and explicit consent nations. For example, while it was expected that next-of-kin approval would be required for procurement in all explicit consent nations, we were surprised to learn the same is true in many nations with presumed consent and that most countries permit next-ofkin to object to donation. Furthermore, of the 19 presumed consent nations that provide a method for individuals to express a wish to be a donor, 15 nations still require the next-of-kin's authorization for organ procurement even when the deceased has registered a wish to become a donor. Deceased donation rates without context can also be misleading. For example, according to the Global Observatory on Donation and Transplantation, Spain (a presumed consent nation) has the highest deceased donation rate per million population (p.m.p.) (34.13 p.m.p.) [95]. However, the founder and director of the Organizacion Nacional de

^bNext-of-kin must be present in the hospital at the time of donation for their opinion to be considered.

^cThe transplant co-ordinator has the discretion to choose if the next-of-kin's permission is necessary. In addition, there is an authorized law agent in attendance during procurement.

^dThe next-of-kin are informed of the intended procurement but permission is not explicitly asked. An objection will be respected.

eIf the deceased expressed their wish to donate, then only they can revoke the decision and upon death their decision will be respected and next-of-kin will not be able to revoke it.

Legally, the next-of-kin's permission is not required if no objection is made, but if there are doubts, the next-of-kin are consulted.

^gPresumed consent is only practiced if the next-of-kin are unreachable or unknown.

hWhen the deceased's wishes are unknown, the next-of-kin is asked what the deceased's opinion on organ donation was. However, if the next-of-kin objects to donation the removal will not occur.

ⁱIn rare cases where the next-of-kin raises an objection against donation the physician can decide not to proceed with removal, if he/she feels continuing would have a major negative impact on the next-of-kin.

^jIf next-of-kin do not object, procurement will proceed under the presumption of consent. However, next-of-kin have a legal right to object and must be informed of this right. If they cannot be reached, donation may not occur.

Table 3. Role of next-of-kin in explicit consent nations^a

	1	
Nation	Next-of-kin's authorization is required if deceased's wishes are unknown	Next-of-kin's consen is required even if deceased's wishes are documented
Australia	Yes	Yes
Brazil	Yes	Yes
Canada	Yes	Yes
Cuba	Yes	Yes
Denmark	Yes	Yes
Estonia	Yes	Yes
Germany	Yes	Yes
Iceland	Yes	Yes
India	Yes	Yes
Ireland	Yes	Yes
Israel	Yes	Yes
Japan	Yes	Yes
Kuwait	Yes	Yes
Lithuania	Yes	Yes
Malaysia	Yes	Yes
Malta	Yes	Yes
Mexico	Yes	Yes
Netherlands	Yes	No ^b
New Zealand	Yes	Yes
Philippines	Yes	Yes
Romania	Yes	No ^c
Saudi Arabia	Yes	Yes
South Africa	Yes	Yes
South Korea	Yes	Yes
Switzerland	Yes	Yes
Thailand	Yes	Yes
UK	Yes	Nob
USA	Yes	No ^d
Venezuela	Yes	Yes

^aIn accordance with the lack of assumption of consent in explicit consent, all nations with explicit consent systems in this study approached the next-of-kin about organ donation (whether the deceased's wishes to be a donor were known or unknown).

Trasplantes (Spain's governing transplantation organization) has repeatedly noted that Spain's high levels of deceased donation should be attributed to its 'Spanish Model' rather than its legislation [14, 96, 97]. In Spain, transplant co-ordinators are required by law to search for a refusal by the deceased but since there is no national non-donor registry and most individuals do not record their decision (e.g. by carrying a donor card), the next-of-kin are consulted as a proxy decision-maker [98]. In addition, a series of organizational measures including a multi-level transplant coordinator network are used to facilitate transplantation [99]. It remains unclear whether the Spanish Model is feasible for nations with different infrastructure and economic constraints. An interesting comparison is the USA, which has the third highest rate for deceased donation across all nations and the highest rate amongst nations with explicit consent (26.27 p.m.p.) [95]. The USA has focused on maximizing the consent rate from next-of-kin. Available data

show that the proportion of families that refuse donation varies considerably in both explicit and presumed consent nations, although on average both consent systems have a family refusal rate of approximately 34–38% [18]. Unfortunately, data on family refusals are very limited, and this value should be interpreted with caution since values are not available from all nations, rendering the rate to be inconclusive. Even so, previous work and our review both suggest that improvement of factors such as next-of-kin consent may have a larger and more immediate effect on transplantation rates than legislative changes [15]. Our results suggest that the next-of-kin strongly influence the decision to pursue organ donation in both consent systems. Future studies investigating the relationship between family refusals and donation rates are warranted.

Some donation programs have recognized this area of opportunity and are trying to improve next-of-kin authorization through the transplant co-ordinator. Training programs, such as the European Donor Hospital Education Programme (EDHEP) and the Donor Action Program, are designed to help improve the transplant staff's communication about death and donation to the next-of-kin [92,100– 102]. There has also been a focus on the dialogue between the co-ordinator and the next-of-kin. The 'presumptive approach' utilizes assumptive language, for example saying 'when you decide to donate' instead of 'if you decide to donate' [103]. The style has been criticized as undermining free and informed consent [104]. A less assumptive approach is used by some transplant co-ordinators in presumed consent European nations, wherein they ask the next-of-kin what the deceased would have wanted instead of explicitly asking for consent. Proponents of this method argue that the burden of the decision is placed back on the deceased instead of the next-of-kin [92]. Encouragingly, this style is not limited to presumed consent nations and is meant to be part of 'first person consent' [105]. Future studies on the exact phrasing transplant coordinators employ when approaching the next-of-kin about donation and variations in practice worldwide are warranted.

The limitations of our study are that we were unable to describe practices in 16 (25%) nations where transplantation is performed because of unreliable or unavailable data. We also dichotomized data for comparison reasons; however, it should be emphasized that these data are highly nuanced. However, our study does have a number of strengths. To our knowledge, this is the first comprehensive study to compare the authority of the next-of-kin in organ donation decision making in nations with explicit and presumed consent. We collected data from 54 nations to provide a broad overview of the issue, and we included nations from all five major regions as defined by the United Nations [106]. We only reported data collected and confirmed by health professionals to ensure accuracy.

It is important to emphasize that deceased donation programs are complex, affected not only by law, administration and infrastructure but also ideology and values. It is improbable that any single strategy or approach will cause a marked improvement on deceased donation rates. While presumed consent nations have demonstrated higher rates of deceased donation, the authority of the

^bA strong objection by the next-of-kin donation will stop procurement to avoid causing a major negative impact on the next-of-kin.

^cPermission is not formally asked or required, an objection will be respected.

dStates with first person consent make the deceased's registered wishes paramount and procurement can occur with consent from the next-of-kin. However next-of-kin are required for a medical and social history of the potential donor before procurement can occur [M. Devenny (personal communication)].

next-of-kin in the procurement process is a feature policy makers should factor into their decision when deciding whether to switch to presumed consent legislation. When an individual dies, best methods to support the wishes of the deceased, the wishes of the next-of-kin and the practice of transplantation remain a focus for research and quality improvement.

Supplementary data

Supplementary data are available online at http://ndt.oxfordjournals.org.

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